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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,190	11/13/2001	Kazutoh Takesako	1422-0502P	6479

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/08/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/987,190

Applicant(s)

TAKESAKO ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5 and 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/262,856.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Applicants response filed on 3/27/03 is acknowledged. Claims 1-20 are pending in the application.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/262,856, filed on 3/4/99. Applicant is advised to update the status of parent application, now U.S. Patent 6,333,164.

Information Disclosure Statement

3. Information Disclosure Statement filed on 11/13/01 (Paper # 4) is acknowledged and a signed copy is attached to this Office action.

Election/Restriction

4. Applicant's election of Group I Claims 1-6 with respect to SEQ.ID.NO: 2 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that SEQ.ID.NO: 2 is a partial amino acid sequence originated from a fungal antigen of 25 kD. SEQ.ID.NO: 6 is the amino acid sequence of entire protein and SEQ.ID.NO: 8 is the nucleotide sequence encoding SEQ.ID.NO: 6. Accordingly these three sequences share common structural sequences. This is not found persuasive.

Applicant elected a nucleic acid encoding fungal antigen comprising an antigenic protein from *Candida albicans*, where in said antigenic protein comprises the partial amino acid sequence as shown in SEQ.ID.NO: 2. The specification, page 120, lines 8-11 recite that oligonucleic acid SO1 (SEQ.ID.NO: 11) and SO2 (SEQ.ID.NO: 12) were deduced to encode SEQ.ID.NO: 2. The examiner carefully looked at the claimed subject matter and reviewed the specification and found no common structure between nucleic acid encoding

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SEQ.ID. NO: 2, 6 and 8. Therefore, the inventions are properly restricted under 35 U.S.C.

121. The requirement is still deemed proper and is therefore made FINAL.

5. Claims 4 (d) and 6 are under examination with respect to SEQ.ID.NO: 2.

Applicant is advised to amend the claim 4 to restrict to SEQ.ID.NO: 2. Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, said election made in Paper # 6.

6. Claims 1-3⁵ and 7-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim objections and informalities

7. Claim 4 is objected to because of the following informalities: The elected invention is drawn to a nucleic acid encoding a fungal antigen comprising SEQ.ID.NO: 2 and has a molecular weight 25,000 Daltons, said election made Paper No. 6. Applicant is advised to recite the limitation of (d) only in to independent claim 4.

Claim 6 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim(s) in independent form.

The recitation " a nucleic acid encoding a polypeptide" in claim 6, reads on any nucleic acid that encodes a polypeptide and broadens the scope of this dependent claim. The Independent claim 4 is limited to a nucleic acid encoding fungal antigen comprising an antigenic protein from *Candida albicans*, wherein said antigenic protein comprises partial amino acid sequence as shown in SEQ.ID.NO: 2 and is limited to fungal antigen. Therefore, appropriate correction is required.

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In claim 4, line 5 originated should be changed to originating.

In claim 4, line 8, 25,000 should be changed to 25,000 Daltons.

Claim Rejections - 35 USC 101

8. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 4 and 6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is drawn to a nucleic acid encoding a protein from *C.albicans* and reads on a product of nature. Products of nature are not patentable because they do not reflect the "hand of man" in the production of the product or manufacturing process. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested to include the terminology "an isolated protein" to overcome the rejection.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 6 are rejected as being vague and indefinite for the recitation of vaccine activity or an allergen activity. What are the metes and bounds of vaccine activity and allergen activity?

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Claim 6 is rejected as being vague and indefinite for the recitation of "capable of ". The expression "capable of " used in the claim renders the claim indefinite because the metes and bounds of the term "capable of " are unclear.

Claim Rejections - 35 USC 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Shen et al 1989 (Clinical and Experimental Allergy, Vol, 19: 191-196).

Claim 6 is drawn to a nucleic acid encoding a peptide having vaccine activity or an allergen activity, wherein said nucleic acid is capable of hybridizing with a nucleic acid of claim 4.

Shen et al disclose isolated *C.albicans* from clinical specimens. Cultured cells were washed and resuspended in buffer and sonicated (see page 192 under antigenic preparation). The sonicated preparation disclosed by Shen et al inherently comprise a nucleic acid encoding a peptide having an allergen activity because the sonicated preparation contained allergenic antigens that are encoded by a nucleic acid (i.e., reactive to IgE, seepage 193, right column through page 194, figure 2 and Table 1) and is capable of hybridizing with the nucleic acid of claim 4. Thus the prior art anticipated the claimed invention.

Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious

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difference between the claimed product and the product of the prior art See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

14. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Ishiguro et al 1992 (*Infection and Immunity*, Vol, 60:1550-1557).

The claim is drawn to a nucleic acid encoding a fungal antigen comprising an antigenic protein having vaccine activity or an allergen activity from *Candida albicans*, wherein said antigenic protein comprises the partial amino acid sequence as shown in SEQ.ID.NO: 2, and has a molecular weight of 25kD by SDS-PAGE.

Ishiguro et al discloses crude whole cell extract from *Candida albicans* cells (see page 1551, right column, last paragraph). Antigens were isolated by gel- electrophoresis from crude extract (see figure 1) Antigen 25kD was strongly stained and reacted with IgE antibody indicating that this 25kD antigen had allergen activity (see figure 1 and Table 1). Therefore, the disclosed crude extract by Ishiguro et al inherently comprise a nucleic acid encoding an antigenic protein having allergen activity from *Candida albicans*, said protein had a molecular weight of 25kD by SDS-PAGE. Characteristics such as the partial amino acid sequence as shown in SEQ.ID.NO: 2 is considered inherent property of 25kD antigen. Thus the prior art anticipated the claimed invention.

Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Status of claims

15. No claims are allowed.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 A.M. to 4:00 P.M. EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

6/25/03

LTS
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600